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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PF-0628 PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/25499	International filing date *(day/month/year)* 29 OCTOBER 1999	Priority date *(day/month/year)* 29 OCTOBER 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant INCYTE PHARMACEUTICALS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 MAY 2000	05 APRIL 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Jayce Bridgers for ROBERT LANDSMAN
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998)*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/25499

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-53, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

[X] the claims:
pages 54-55, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of

[X] the drawings:
pages 1-22, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

[X] the sequence listing part of the description:
pages 1-7, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[X] contained in the international application in printed form.

[X] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 17, 18, 20

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _ are so unclear that no meaningful opinion could be formed *(specify)*.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17,18,20 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	19	**YES**
	Claims	1-16	**NO**
Inventive Step (IS)	Claims	19	**YES**
	Claims	1-16	**NO**
Industrial Applicability (IA)	Claims	1-16 and 19	**YES**
	Claims	NONE	**NO**

2. citations and explanations (Rule 70.7)

Claims 1-16 lack novelty under PCT Article 33(2) as being anticipated by Yuasa et al. Yuasa et al. teach a substantially purified polypeptide of a fragment of SEQ ID NO:1 and 2 as well as an isolated polynucleotide fragments of SEQ ID NO:3 and 4 encoding these fragments. It would be inherent that Yuasa et al. also were in possession of the complement to said polynucleotide. Yuasa et al. also teach a method for detecting a polynucleotide in a sample by using hybridization probes which form complexes with the polynucleotides of the invention. RT-PCR was also used to amplify the polynucleotide of interest. Yuasa et al. also have produced recombinant polypeptides of the invention and have raised antibodies to these polypeptides.

Claims 1-16 lack novelty under PCT Article 33(2) as being anticipated by Kallin et al. Kallin et al. teach a substantially purified polypeptide of a fragment of SEQ ID NO:1 and 2 as well as an isolated polynucleotide fragments of SEQ ID NO:3 and 4 encoding these fragments. It would be inherent that Kallin et al. also were in possession of the complement to said polynucleotide. Kallin et al. also teach a method for detecting a polynucleotide in a sample by using hybridization probes which form complexes with the polynucleotides of the invention. The polynucleotides of interest were amplified in E. coli. Kallin et al. also have produced recombinant polypeptides of the invention and have raised antibodies to these polypeptides.

Claims 1-16 lack novelty under PCT Article 33(2) as being anticipated by Yu et al. Yu et al. teach a substantially purified polypeptide of a fragment of SEQ ID NO:1 and 2 as well as an isolated polynucleotide fragments of SEQ ID NO:3 and 4 encoding these fragments. It would be inherent that Yu et al. also were in possession of the complement to said polynucleotide. Yu et al. also teach a method for detecting a polynucleotide in a sample by using hybridization probes which form complexes with the polynucleotides of the invention. The polynucleotides of interest were amplified by PCR. Yu et al. also have produced recombinant polypeptides of the invention and have raised antibodies to these (Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII **Sheet 10**

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7):C12Q 1/68; A01N 37/18, A61K 38/00; C07K 14/00, 16/00, 17/00, 2/00, 4/00, 5/00, 7/00, 1/00; C07H 21/04 and US Cl.:435/6; 514/2; 530/300, 350, 387.1; 536/23.5

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
polypeptides.

Claim 19 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of treating or preventing a disorder associated with decreased expression of TM4P activity.

Claims 1-16 and 19 meet the criteria set out in PCT Article 33(4) for industrial applicability.

In the Response to the Written Opinion, filed 23 February 2001, Applicants traversed the Examiner's objections. However, no arguments were presented, but Applicants state that they reserve the right to address these and other objections in the future.

---------- NEW CITATIONS ----------
NONE